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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,186	01/22/2002	John Adamou	PF129C2	9920

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EXAMINER
PAK, MICHAEL D

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,186	ADAMOU ET AL.	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-9 are, drawn to an isolated polynucleotide, classified in Class 536, subclass 23.5; a vector (435/320.1); a host cell (435/240.1+); a process of producing polypeptide (435/69.1); and a process for producing cells (435/172.3).

Group II. Claims 10-11, and 17 are, drawn to a polypeptide, classified in Class 530, subclass 300+.

Group III. Claim 12 is, drawn to an antibody, classified in Class 530, subclass 387.1.

Group IV. Claim 13 is, drawn to a compound which activates, may be classified in any number of Classes including 424 and 514.

Group V. Claim 14 is, drawn to a compound which inhibits activation, may be classified in any number of Classes including 424 and 514.

Group VI. Claim 15 is, drawn to a method for the treatment having the need of activation of a CGRP polypeptide, may be classified in any number of Classes including 424 and 514.

Group VII. Claim 16 is, drawn to a method for the treatment of a patient having a need to inhibit activation of a CGRP polypeptide, may be classified in any number of Classes including 424 and 514.

Group VIII. Claim 18 is, drawn to a process for identifying antagonists and agonists to the CGRP receptor, classified in Class 435, subclass 7.20.

Group IX. Claim 19 is, drawn to a process for determining whether a ligand not known to be capable of binding to the polypeptide can bind, classified in Class 435, subclass 7.2.

Group X. Claim 20 is, drawn to a process for diagnosing a disease, classified in Class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Group I is related to group II because the DNA of group I encodes the CGRP receptor of group II. Group I is related to groups III- V because the DNA of group I encodes the CGRP receptor and the CGRP receptor interacts with groups III-V. Group I is directed to products that are distinct both structurally and functionally from products of groups II-V. Therefore, group I is not required for the other groups and patentably distinct from other groups. The polynucleotides of group I is different from the polypeptides of group II and the antibodies of group III, and the compounds of groups IV-V. The polynucleotides of group I can be used for other purposes than products of groups II-V. The polynucleotides of group I can be used for gene therapy whereas the proteins of group II can be used for binding assays, the antibodies of group III can be used for immunoprecipitation of CGRP, the compound of group IV can be used to activate signal transduction, and the compound of group V can be used to inhibit activation.

Group I is not related to methods and processes of groups VI, VII, and IX because the experimental materials and products used in the methods of groups VI, VII, and IX are independent of the polynucleotides of group I. The methods of groups VI,

VII, and IX do not require the isolated nucleic acid of group I. Therefore, group I is not required for groups VI, VII, and IX and patentably distinct from the other groups. The DNAs of group I can be used independently of the methods of groups VI, VII, and IX. The DNAs of group I can be used for hybridization whereas the methods of groups VI-VII can treat patients and the processes of group IX identify agonists and antagonists.

Inventions group I and group VIII or X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the isolated polynucleotide of group I may be used for gene therapy which is different from group VIII's process for identifying agonists and antagonist and group X's process for diagnosing a disease.

Group II is related to group III since group II can be used to generate the antibodies of group III. Group II is directed to products that are distinct both structurally and functionally from products of group III. Therefore, group II is not required for the other groups and patentably distinct from other groups. The polypeptide of group II can be used independently of the antibodies of group III. The polypeptides may be used to study protein domain interactions whereas the antibodies can be used to localize the anatomical location of the antigen in situ.

Inventions of group II and groups IV-IX are related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the

following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the CGRP receptor product of group II may be used for generating antibodies which is different from the invention of groups IV-IX which are directed to activators, inhibitors, agonists, antagonists, and unknown ligands of the receptor.

Group II is distantly related to group X since group II can be synthesized using certain nucleic acids used in group X. Group II is directed to products that are distinct both structurally and functionally from materials used in the methods of group X. Therefore, group II is not required for the other groups and patentably distinct from other groups. The polypeptide of group II can be used independently of the methods of group III. The polypeptides may be used to study protein domain interactions whereas the method is used for DNA hybridization.

Group III is directed to antibody products which are distinct both structurally and functionally from compounds of groups IV-V. Furthermore, group III is not required for the use of the methods of groups VI-X and are patentably distinct from other groups. The antibodies of group III can be used independently of the compounds of groups IV-V and methods of groups VI-X. The antibodies may be used to study protein domain interactions whereas the activators and inhibitors of groups IV-VII can be used for signal transduction studies or treatments. The processes of groups VIII and IX can use binding assays while the process of group X uses DNA hybridization.

Group IV is directed to products which are distinct both structurally and functionally from the compounds of group V. Furthermore, group IV is not required for the use of the methods of groups VII and X and are patentably distinct from other groups. The compounds of group IV can be used independently of the compounds of groups V and methods of groups VII and X. The activators of group IV may be used to activate signal transduction whereas the inhibitors of group V can be used for inhibiting signal transduction studies. The method of group VII can be used in a treatment by inhibiting while the process of group X uses DNA hybridization.

Inventions of group IV and groups VI, VIII, and IX are related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the activator of group IV may be used for generating antibodies which is different from the invention of groups VI, VIII, and IX which are directed to treatments with activators, and processes of identifying agonists, antagonists, and unknown ligands of the receptor.

Group V is directed to products which are not required for the use of the methods of groups VI and X and are patentably distinct from other groups. The compounds of group V can be used independently of the methods of groups VI and X. The inhibitors of group V may be used to inhibit signal transduction whereas the method of group VI

can be used in a treatment by activating while the process of group X uses DNA hybridization.

Inventions of group V and groups VII-IX are related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the activator of group V may be used for generating antibodies which is different from the invention of groups VI-IX which are directed to treatments with inhibitors, and processes of identifying agonists, antagonists, and unknown ligands of the receptor.

The method of group VI is distantly related to the methods of groups VII-X in that CGRP receptor DNA or polypeptide interaction may be used for all the methods. The method of group VI is patentably distinct from the methods of groups VII-X because they have different goals, method steps, and starting materials, and are not required one for the other. The method of treatment with activators of group VI use different pharmaceutical composition from method of group VII which uses the inhibitors. The methods of groups VIII and IX are directed to methods of identifying agonists, antagonists, or potential ligands. The method of detecting of group X are directed to DNA hybridization.

The method of group VII is distantly related to the methods of groups VIII-X in that CGRP receptor DNA may be used for all the methods. The method of group VII is

patentably distinct from the methods of groups VIII-X because they have different goals, method steps, and starting materials, and are not required one for the other. The method of treatment with inhibitors of group VII are different the methods of groups VIII and IX are directed to methods of identifying agonists, antagonists, or potential ligands. The method of detecting of group X are directed to DNA hybridization.

The method of group VIII is distantly related to the methods of groups IX-X in that CGRP receptor DNA may be used for all the methods. The method of group VIII is patentably distinct from the methods of groups IX-X because they have different goals, method steps, and starting materials, and are not required one for the other. The process of identifying antagonists and agonist of group VIII can be used in signal transduction assays whereas the methods of group IX can be determined using binding assays. The method of detecting of group X are directed to DNA hybridization.

The method of group IX is distantly related to the method of group X in that CGRP receptor DNA or protein may be used for both methods. The method of group IX is patentably distinct from the method of group X because they have different goals, method steps, and starting materials, and are not required one for the other. The process of identifying ligand of group IX can be used in signal transduction assays whereas the method of detecting of group X are directed to DNA hybridization.

For the reasons given immediately above regarding groups I-X, a search and examination of one group is not the same as that for any other group. Therefore, an undue burden would be placed on the examiner to search and examine more than one group of invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications and their recognized divergent subject matter, and because the search required for each group is not required for any of the others, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (571) 272-0879. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-0507.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
28 September 2004